

Orthodontic Design and Production, Inc.

JUN 07 2013

510(k) Summary

510(k) Submitter: Orthodontic Design & Production, Inc.
1370 Decision Street, Suite D
Vista, California 92081

Official Contact Person: Richard Merrell
Regulatory Affairs Manager
Telephone: (760) 734-3995 ext. 25
Facsimile: (760) 734-1735
E-mail: rm@odpinc.com

Date Summary was Prepared: February 8, 2013

Device Trade Name: FastBraces® Ceramic Brackets

Common Name: Orthodontic Ceramic Bracket

Classification Name: Orthodontic Ceramic Bracket, Class II
(21 CFR 872.5470, Product Code: NJM)

Predicate Device: K922499, Reflections Ceramic Dental Bracket

Description of Device:

Ceramic orthodontic brackets are small devices that are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist. Ceramic orthodontic brackets are primarily offered as an aesthetic alternative to metal orthodontic brackets. They are close to natural tooth coloring, and blend in well enough that they are not as visible as metal brackets. This aesthetic look is popular with many patients, and especially older patients. Ceramic orthodontic brackets have been in use throughout the orthodontic industry for approximately thirty years.

Like its predicate, FastBraces® ceramic brackets are manufactured from polycrystalline alumina (ceramic) material, and have bases that are designed to provide maximum adhesion to the tooth while still allowing for easy and complete removal when necessary. The brackets incorporate a water soluble color placement dot as an indicator for correct selection of brackets for each tooth.

Like its predicate, FastBraces® ceramic brackets do not incorporate medicinal substances, tissues, or blood products. They do not include software or accessories, and are delivered non-



Orthodontic Design and Production, Inc.

sterile to the end user. Ceramic brackets are intended to be used only once by a single patient. Product labels contain appropriate "do not reuse" symbols. Orthodontic ceramic brackets are used for the duration of orthodontic treatment, which can last more than 30 months. During this time, the devices remain in direct contact with the patient's oral cavity. Because the intended purpose of the device is clearly understood by licensed orthodontists, instructions for use are not provided.

With the exception of the materials from which they are constructed, the form, fit, and function of orthodontic ceramic brackets are identical to those of traditional metal orthodontic brackets. Orthodontic ceramic brackets, like metal brackets achieve their intended purpose (to move teeth into a desired position) through industry standard "prescriptions" that are pre-programmed into the design of the brackets. Specific torques, angulations, and distal offset dimensions are designed into each bracket, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick).

Ceramic brackets are designed with tie wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded corners and edges, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment. These design characteristics allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket's archwire slot.

Intended Use:

FastBraces® Ceramic Brackets are intended for orthodontic movement of natural teeth.

Technological Characteristics:

The design, material, and intended use of FastBraces® Ceramic Brackets are similar to the predicate device.

Regarding design, FastBraces® ceramic brackets and their predicate both incorporate specific torques, angulations, and distal offset dimensions, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick). They both feature tie wing undercut spaces for orthodontic ligatures, have a molded ceramic bracket bodies with rounded corners and edges for patient comfort, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment.

Regarding materials, FastBraces® ceramic brackets and its predicate are manufactured from polycrystalline alumina (ceramic) material, which is of known biocompatibility in the oral environment.

Regarding intended use, the design characteristics of FastBraces® ceramic brackets and its predicate allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket's archwire slot.



Orthodontic Design and Production, Inc.

Substantial Equivalence:

FastBraces® Ceramic Brackets are safe and effective for their intended use in orthodontic treatment, and perform at least as well as the predicate device listed above. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility. Minor design changes are the only variations as compared to the predicate. There are no changes in the intended use or the fundamental scientific technology.

Device Material:

The FastBraces® Ceramic Bracket and its predicate are both made of ceramic tri polycrystalline alumina, which has a well-documented history of biocompatibility within the oral environment. ODP has prepared a biocompatibility summary report in accordance with ISO 10993-1:2009, which is located in Section 15 of this submission. Because the materials from which the devices are constructed are well established in the orthodontic industry, product testing in regards to biocompatibility was not performed. Instead, a literature review has been conducted in accordance with ISO 10993-1:2009, Annex C.

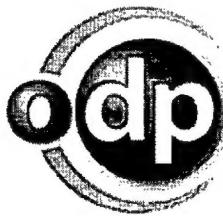
Device Design:

FastBraces® Ceramic Brackets and its predicate both have tie wing undercut spaces for orthodontic ligatures. They each have true-twin tie wings, i.e. four tiewings, for versatile use with auxiliaries. FastBraces® Ceramic Brackets and its predicate also contain base flanges for bracket placement and adhesive flash cleanup. FastBraces® Ceramic Brackets and its predicate contain a molded ceramic bracket body with rounded corners and edges, and a round hook on the distal-gingival tiewings. Like its predicate, certain FastBraces® Ceramic brackets contain vertical slot and stress concentrators to facilitate debonding of the bracket from the tooth.

Nonclinical Performance Testing:

The nonclinical performance testing analysis shows that FastBraces® Ceramic Brackets perform comparably to the predicate device as follows:

1. Shear Test measures shear strength required to remove a bonded bracket from a substrate when a force is applied in the occlusal direction. The test results showed that the bond strength of FastBraces® Ceramic Brackets are comparable to the predicate, and exceed the minimum bond strength required to affix the bracket to the tooth.
2. Wire Torque Test measures the torsional force required to break a bonded bracket when a rectangular wire is twisted in the wire slot. The test results showed comparable bracket strengths, with the Fast Braces® wire torque test averaging 3,473 gm Force, and the predicate device averaging 3,333 gm Force before breakage occurred.
3. Wire Drag Test measures the force required to drag a ligated stainless steel wire through the slot of a bonded bracket. The test results showed lower forces were required to drag the Fast Braces® ceramic bracket along a ligated stainless steel wire than the predicate, indicating better sliding mechanics during treatment.
4. Bracket Removal Test evaluates the visual condition of a bonded bracket after twisting it off the substrate with pliers. The Fast Braces® bracket removal test resulted in less bracket fracturing as compared to the predicate device when removing the bracket from a substrate using pliers.



Orthodontic Design and Production, Inc.

Clinical Performance Testing:

No clinical performance testing was conducted on FastBraces® Ceramic Brackets.

Conclusion:

ODP's FastBraces® Ceramic Brackets are standard orthodontic appliances that are similar to those that have been legally marketed and used safely and effectively for many years in the clinical environment. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility.

There are no major differences between the FastBraces® Ceramic Brackets and the predicate device cited. Therefore, FastBraces® Ceramic Brackets raise no new issues of safety or effectiveness.

FastBraces® Ceramic Brackets are designed and manufactured to industry-standard specifications using materials that have a well established and documented history of biocompatibility within the oral environment. As designed, FastBraces® Ceramic Brackets are as safe and effective as the predicate device, and are determined to be substantially equivalent to the referenced predicate device currently on the market. Taking these factors into account, it can be safely concluded that ODP's FastBraces® Ceramic Brackets are of low risk to the end user, are clinically safe, and perform at least as well as the predicate device referred to herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Mr. Richard Merrell
Regulatory Affairs Manager
Orthodontic Design and Production, Inc.
1370 Decision Street, Suite D
Vista, CA 92081

Re: K130446
Trade/Device Name: FastBraces® Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: April 10, 2013
Received: April 15, 2013

Dear Mr. Merrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Mary S.
Runner-S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Orthodontic Design and Production, Inc.

Indications for Use

510(k) Number:

K130446

Device Name:

FastBraces® Ceramic Brackets

Indications for Use:

FastBraces® Ceramic Brackets are indicated for orthodontic movement of natural teeth.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen
2013.06.07 10:48:08 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130446